



## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>6</sup> : <b>A61F 2/06, A61B 17/12</b>	<b>A1</b>	(11) International Publication Number: <b>WO 97/46175</b>
(43) International Publication Date: 11 December 1997 (11.12.97)		
(21) International Application Number: <b>PCT/US97/09654</b>	(81) Designated States: JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).	
(22) International Filing Date: <b>3 June 1997 (03.06.97)</b>		
(30) Priority Data: <b>08/658,137 4 June 1996 (04.06.96) US</b>	<b>Published</b> <i>With international search report.          Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>	
(71) Applicant: <b>MEDTRONIC, INC. [US/US]; 7000 Central Avenue, N.E., Minneapolis, MN 55432 (US).</b>		
(72) Inventors: <b>EVANS, Michael, A.; 637 Webster Street, Palo Alto, CA 94301 (US); KINNEY, Edward, V.; 7607 Garden View Court, Louisville, KY 40220 (US); COOMBS, Craig, J.; 1446 Dana Avenue, Palo Alto, CA 94301 (US); DE CICCO, Dino; 935 Pomeroy Avenue, No. 18, Santa Clara, CA 95015 (US); TOLOMEO, Deborah; 666 South El Monte, No. 8, Los Altos, CA 94022 (US).</b>		
(74) Agents: <b>BARRISH, Mark, D. et al.; Townsend and Townsend and Crew LLP, 8th floor, Two Embarcadero Center, San Francisco, CA 94111-3834 (US).</b>		
(54) Title: <b>ENDOLUMINAL PROSTHETIC BIFURCATION SHUNT</b>		
(57) Abstract		
<p>Methods, systems, and devices seal off the branch port of a bifurcated endoluminal prosthesis to transform the bifurcated prosthesis to a single-lumen prosthesis. These methods and devices are available for fallback procedures when the deployment of a bifurcated endoluminal prosthesis is found to be impracticable. By effectively sealing off the second branch port, the attending physician is able to completely isolate an aneurysm or other disease of the vasculature. Where it is necessary and/or desirable to provide fluid communication between the trunk lumen and the second branch lumen, a separate passage may be provided between the first and second branches of the body lumen system.</p>		

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## ENDOLUMINAL PROSTHETIC BIFURCATION SHUNT

### CROSS REFERENCE TO RELATED APPLICATION

This application is a continuation-in-part of, and claims priority from, U.S. Patent Application Serial Number 08/658,137, filed June 4, 1996, the full disclosure of which is incorporated by reference.

### BACKGROUND OF THE INVENTION

#### I. FIELD OF THE INVENTION

The present invention relates generally to tubular endoluminal prostheses, such as grafts, stents, stent-grafts, and the like. More particularly, the present invention provides methods, systems, and devices for sealing or occluding a branch of a branching endoluminal prosthesis, particularly when the branch to be sealed has been found to be incorrectly positioned, inaccessible, or otherwise detrimental to a prosthetic therapy for abdominal and other aneurysms, and for treatments of other branched body lumens.

Vascular aneurysms are the result of abnormal dilation of a blood vessel, usually resulting from disease and/or genetic predisposition, which can weaken the arterial wall and allow it to expand. While aneurysms can occur in any blood vessel, most occur in the aorta and peripheral arteries, with the majority of aortic aneurysms occurring in the abdominal aorta, usually beginning below the renal arteries and often extending into one or both of the iliac arteries.

Aortic aneurysms are most commonly treated in open surgical procedures, where the diseased vessel segment is bypassed and repaired with an artificial vascular graft. While considered to be an effective surgical technique, particularly considering the alternative of the usually fatal ruptured abdominal aortic aneurysm, conventional vascular

graft surgery suffers from a number of disadvantages. The surgical procedure is complex and requires experienced surgeons and well equipped surgical facilities. Even with the best surgeons and equipment, however, patients suffering from such aneurysms are often elderly and weakened from cardiovascular and other diseases, which reduces the number of eligible patients. Even for eligible patients prior to rupture, conventional aneurysm repair has a relatively high mortality rate, usually from 2 to 10%. Morbidity related to the conventional surgery includes myocardial infarction, renal failure, impotence, paralysis, and other conditions. Additionally, even with successful surgery, recovery takes several weeks and often requires a lengthy hospital stay.

In order to overcome all or some of these drawbacks, a variety of endovascular prosthesis placement techniques have been proposed for the treatment of aneurysms. Although some of these proposed techniques appear very promising, known methods and apparatus suffers from undesirable limitations in at least some aspect. Of particular relevance for the present invention, endovascular therapies for aneurysms which extend from the abdominal artery down along one or both iliac arteries, sometimes called aortoiliac aneurysms, have proven to be particularly problematic.

Endovascular therapies for aortoiliac aneurysms are complicated by the difficulty of sealing the aneurysm from the blood flow through the aorta and the first and second iliac arteries, while maintaining that blood flow to the separate branches of the vascular system. One approach which has been used to isolate such aneurysms was described by Dr. Parodi in "Endovascular Repair of Abdominal Aortic Aneurysms and Other Arterial Lesions", J. Vasc. Surg. 21:549-57 (April, 1995). This "single-lumen" method involved deploying an unbranching tubular prosthesis from the healthy aorta above the aneurysm, through the aneurysm itself, and into one of the two iliac arteries, so that all blood flowing through the aorta was channelled into that single iliac. A portion of the blood is then transferred to the alternate portion of the vascular system (normally supplied by the alternate iliac) through a

"femorofemoral bypass," a prosthetic vascular graft having an end-to-side anastomosis with each of the femoral arteries. Advantageously, known femorofemoral bypass procedures involve substantially less patient trauma than conventional invasive aortic aneurysm repair. The unused iliac artery is then occluded with detachable balloons or ligation.

Although this single-lumen method has proven to be fairly effective, the resulting blood flow path is somewhat less than ideal. The entire aortic blood flow must pass through a single iliac artery, and then separates downstream of the hypogastric artery into left and right femoral portions, providing a tortuous route which imposes a significant strain on the heart. Nonetheless, this procedure does have the advantages of only requiring a single healthy iliac artery for the endoluminal prosthesis to seal and anchor against, and is clearly preferable to allowing blood to continue to flow into a weak or ruptured aneurysm.

More recently, endovascular deployment of a bifurcated tubular prosthesis has been proposed as a therapy for aortoiliac aneurysms. Bifurcated prostheses generally have a trunk portion with a relatively large lumen for deployment in the aorta, and first and second branch portions with smaller branch lumens for deployment within each of the iliac arteries. The deployed trunk and branch portions preferably seal to each other and to the healthy vascular walls beyond the aneurysm to isolate the aneurysm from the bloodstream. Advantageously, the aortic blood flow enters the trunk prosthetic lumen, is separated into the two branch prosthetic lumens, and then flows into each of the iliac arteries in a path that approximates that of a normal, healthy vascular system. Unfortunately, deployment of such bifurcated prostheses across the aortoiliac junction is more complex than deployment of a single-lumen prosthesis.

A variety of minimally invasive techniques have been suggested for deployment of these bifurcated prostheses, including *in situ* assembly of multiple prosthetic modules, initial positioning of both prosthetic branch portions within a single iliac artery, initially deploying one of the branches

folded up along the aorta, or the like. Regardless of the specific deployment procedure used, a tubular prosthesis having a lumen initially spans from the healthy portion of the aorta, through the aneurysm, and into one of the two iliac arteries, as was also true of the single-lumen prosthetic method. However, these techniques differ from the single-lumen method in that a branch port for the alternate iliac artery is disposed between the upstream and downstream ends of the tubular bifurcated prosthesis. Furthermore, proper initial deployment of the bifurcated prosthesis generally requires that the second branch port be properly oriented toward the alternate iliac.

Completing deployment of the bifurcated prosthesis generally involves positioning of the second branch portion in the alternate iliac. Oftentimes, the second branch portion is deployed through a catheter which extends from the iliac to the branch port of the bifurcated prostheses, thereby assembling the continuous bifurcated prosthetic lumen *in situ*. Such deployment of the second branch portion can be very straightforward, and *in situ* assembly of bifurcated prostheses appears to hold significant promise for many abdominal aortic aneurysm patients.

Unfortunately, bifurcated prosthetic therapies are not without their own disadvantages. Aortic aneurysms vary widely in location, size, and the distended shape of the aneurysm itself. Particularly in the advanced stages, aneurysms can also distort the aorta and iliac arteries surrounding the aneurysm, and tend to collect large amounts of thrombus. Diseased iliac arteries may be narrow due to plaque buildup, so that the remaining lumen is highly tortuous. In fact, diseased vessel tortuosity may prevent catheter or even guidewire passage. Furthermore, the precise shape and extent of the aneurysm can be very difficult to accurately determine. As a result, the accurate initial deployment of the bifurcated prosthesis, and in particular, the accurate orientation of the branch port, can be problematic. Even when the branch port is positioned as intended, it may turn out to be difficult and/or impossible to effectively deploy the second branch without

rupturing the aneurysm, or without releasing the microthrombus from the distended aneurysm into the blood stream.

Once the physician completes initial deployment of a bifurcated prosthesis, but then finds that it is impossible to complete the deployment so as to seal off the aneurysm, massive surgical intervention is generally required to remove the partially deployed bifurcated prosthesis, and to install a conventional artificial graft. Hence, current minimally invasive bifurcated prosthetic therapies may be performed only after all the preparation, personnel, and equipment for convention aneurysm repair are in place. Clearly, such fallback requirements compromise the advantages of present bifurcated prosthetic therapies.

For these reasons, it would be desirable to provide improved endoluminal prosthetic methods, systems, and devices. It would be particularly desirable to provide endovascular therapies which would allow surgeons to take full advantage of the bifurcated prosthetic methods whenever possible, and to fall back to the single-lumen prosthetic methods when required by a particular patients physiology, or by the events as they actually unfold during initial deployment. It would further be desirable to provide methods and systems which would allow physicians to aggressively pursue the advantageous bifurcated prosthetic techniques, even when it is not entirely certain that those techniques will succeed, but to provide a less invasive fallback procedure if the complete deployment of the bifurcated prosthesis turns out to be impracticable.

## II. DESCRIPTION OF THE BACKGROUND ART

Co-pending U.S. Patent Application Serial No. 08/615,697, filed March 13, 1996, (Attorney Docket No. 16380-004100) the full disclosure of which is incorporated herein by reference, describes exemplary modular bifurcated prosthetic structures which are highly adaptable to a wide variety of patient physiologies. Provisional U.S. Patent Application Serial No. 60/008,254, filed December 1, 1995 (Attorney Docket No. 16380-003400), also incorporated herein by reference,

describes bifurcated modular prosthetic structures and methods for assembling them *in situ*.

Dr. Parodi's article "Endovascular Repair of Abdominal Aortic Aneurysms and Other Arterial Lesions", J. Vasc. Surg. 21:549-57 (1995), has been described above. U.S. Patent No. 5,499,995 describes a device and method for blocking a body passageway by inserting an expandable frame into the passageway and expanding the frame therein. U.S. Patent No. 5,489,295, describes an endovascular graft having a bifurcation, and a method for deploying the bifurcated graft by pulling one leg from the aorta down into an iliac.

#### SUMMARY OF THE INVENTION

The present invention provides methods, systems, and devices which allow a surgeon to seal at least one branch port of a bifurcated endoluminal prosthesis, thereby effectively allowing the physician to transform a deployed two-branch bifurcated prosthesis to a single-lumen tubular prosthesis. Generally, the methods and devices of the present invention will be available as fallback procedures when the complete deployment of a bifurcated endoluminal prosthesis is found to be impracticable. By effectively sealing off a branch port, the physician is able to completely isolate an aneurysm or other disease of the body lumen, thereby avoiding massively invasive conventional aneurysm repair surgery. Fluid communication between the trunk lumen and the second branch lumen of the body lumen system may be provided by a separate passage between the first and second branches of the body lumen system, for example, with known femorofemoral bypass procedures. The devices and methods of the present invention allow a physician to aggressively pursue the highly beneficial bifurcated endoluminal prosthetic therapies, but then allow the physician to fallback to an effective procedure which avoids the massive surgical intervention generally required to overcome an incomplete bifurcated prosthesis deployment.

As used herein, a "bifurcated" endoluminal prosthesis means an endoluminal prosthesis having at least two branches. Hence, trifurcated prostheses, in which a trunk



lumen is in fluid communication with the lumens of each of three branches, as well as similar prostheses having four or more branches, are all encompassed by the term bifurcated prostheses. Similarly, bifurcated body lumens may also have more than two branch lumens.

In a first aspect, the present invention provides a method for repairing a bifurcated body lumen system. The body lumen system has a trunk lumen in fluid communication with first and second branch lumens at a luminal intersection. A tubular bifurcated endoluminal prosthesis is deployed within the body lumen system so that a trunk portion of the prosthesis extends into the trunk lumen, and a first branch portion of the prosthesis extends into the first branch lumen. A second branch port of the prosthesis is disposed between the trunk and branch portions. The method comprises substantially sealing this second branch port to prevent fluid communication between the prosthetic trunk lumen and the body lumen system through the second branch port. Often times, an alternative passage for fluid communication between the first branch lumen and the second branch lumen of the body lumen system will be provided. For example, when the bifurcated endoluminal prosthesis traverses an abdominal aortic aneurysm, blood flow to the alternative iliac (which would otherwise be blocked by the sealed branch port) will often be provided by a femorofemoral bypass procedure. Preferably, the sealing step comprises deploying a shunt within the bifurcated prosthesis so that the shunt extends from the trunk portion to the branch portion, and so that a membrane of the shunt substantially blocks fluid communication between the prosthetic trunk lumen and the second branch port. This membrane may seal against the lumen of the prosthesis itself, or may extend through the trunk and/or branch portions to seal directly against the surrounding body lumen, and will generally provide a smooth transition from the trunk lumen to the branch lumen of the completed prosthetic lumen system.

In a second aspect, the present invention provides a method for repairing an aneurysm of an abdominal aortic artery adjacent first and second iliac arteries, the method

comprising deploying a bifurcated tubular endoluminal prosthesis within the aneurysm so that a trunk portion of the prosthesis having a trunk lumen extends into the aorta. A first branch portion of the prosthesis having a first branch lumen extends into the first iliac, while a second branch port of the prosthesis is disposed between the trunk and branch portions. A shunt is deployed within the bifurcated prostheses so that the shunt extends from the trunk lumen to the branch lumen, and so that the shunt substantially blocks fluid communication between the prosthetic trunk lumen and the second branch port of the bifurcated prosthesis.

Typically, it will be determined that the second branch port of the bifurcated prosthesis is substantially inaccessible for deployment of a second branch endoluminal prosthesis before the shunt is deployed. To allow blood to flow from the first femoral artery adjacent the first iliac to a second femoral artery adjacent the second iliac, a femorofemoral bypass will often be provided. Additionally, the second iliac between the aneurysm and the femorofemoral bypass will often be occluded to prevent blood from flowing back through that second iliac into the aneurysm.

In another aspect, the present invention provides a shunt for use with a bifurcated tubular endoluminal prosthesis, the bifurcated prosthesis having a branch lumen in fluid communication with a trunk lumen and a branch port disposed therebetween, the shunt comprising a substantially impermeable membrane and a support structure capable of affixing the impermeable membrane within the bifurcated prosthesis so that the impermeable membrane blocks fluid communication between the trunk lumen and the branch port of the bifurcated prosthesis. The shunt, however, will not substantially occlude fluid communication between the trunk lumen and the branch lumen when the membrane is affixed in place by the support structure.

Generally, the support structure comprises a radially expandable tubular body. In some cases, the tubular body comprises a perforate frame, while the membrane comprises a liner supported by the frame. Alternatively, the membrane

may be formed integrally with the tubular body. Regardless, a branch end of the shunt is preferably capable of sealing radially against a surrounding lumen having a branch cross-section, while a trunk end of the shunt opposite the branch end is capable of sealing radially against a surrounding lumen having a trunk cross-section which is at least twice as large as the branch cross-section. The shunt will generally provide a gradually tapered luminal cross-section when deployed to provide a smooth transition, and to avoid stagnation zones which would otherwise promote the formation of thrombus.

In yet another aspect, the present invention provides a system for repairing a diseased body lumen system, the repair system comprising a bifurcated tubular endoluminal prosthesis and a shunt. The bifurcated prosthesis has a trunk portion with a trunk lumen, a first branch portion having a first branch lumen, and a second branch port in fluid communication with the trunk lumen. The shunt includes a substantially impermeable membrane and a support structure capable of fixing the impermeable membrane to the bifurcated prosthesis so that the impermeable membrane blocks fluid communication between the trunk lumen and the second branch port of the bifurcated prosthesis. Optionally, the repair system will further comprise a branch tubular prosthesis having an end which sealingly engages the branch port of the bifurcated prosthesis when expanded therein. This branch prosthesis will typically be used as a preferred alternative to the shunt, the shunt providing a fallback only in the case that deployment of the branch prosthesis proves to be impracticable or ineffective.

In another aspect, the present invention provides a method for repairing a bifurcated body lumen system. The method comprises inserting a bifurcated prosthesis into the lumen system so that a first lumen of the prosthesis sealingly engages a first lumen of the body lumen system, and so that a second lumen of the prosthesis sealingly engages a second lumen of the body lumen system. A port of the prosthesis is adjacent to a third lumen of the body lumen system, and is reversibly sealed to prevent flow through the port.

In another aspect, the present invention provides a tubular body which is radially expandable from a narrow configuration for endoluminal introduction to a large configuration. In the large configuration, the prosthesis has a first lumen, a second lumen in fluid communication with the first lumen, and a reversibly sealed port disposed between the first lumen and the second lumen.

In another aspect, the present invention provides a system for repairing a diseased body lumen. The system comprises a bifurcated endoluminal prosthesis having a port disposed between and in fluid communication with first and second lumens. The prosthesis is radially expandable from a narrow configuration (for introduction into the body lumen) to a larger deployed configuration, and an occluder is disposable in the deployed prosthesis so as to substantially seal the port.

The present invention also provides an endoluminal prosthetic system comprising a first prosthetic module having a first tubular body and a first imageable marker. A second prosthetic module has a second tubular body which can expand radially to engage the first tubular body, and a second imageable marker adapted to provide an image which is different than an image of the first marker.

In yet another aspect, the present invention provides a system for occluding a body lumen. The system comprises a tubular frame having a proximal end, a distal end, and an axis. The frame is resiliently expandable from a narrow configuration to a wide configuration within the body lumen. A liner is supported by the frame, and is adapted to occlude the body lumen when the frame is in the wide configuration. The liner extends axially beyond the frame when the frame is in the narrow configuration.

#### BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a side view of an exemplary cylindrical vascular stent-graft.

Fig. 2 is a prospective view of an exemplary delivery catheter for use with the prostheses of the present

invention, with a portion of the distal end broken away to disclose a prosthesis therein.

Fig. 3 illustrates an exemplary bifurcated endovascular prosthesis having a relatively rigid expanded Y-connector portion, axially flexible branch and trunk portions, and sealing/anchoring cuffs, thereby allowing the bifurcated prosthetic structure to adapt to widely varying luminal geometries.

Fig. 4A illustrates a bifurcated endoluminal prosthetic system which includes a bifurcated endoluminal prosthesis, a branch prosthesis, and a shunt for deployment within the bifurcated prosthesis, the shunt for use if deployment of the branch prosthesis proves impracticable or ineffective.

Fig. 4B illustrates a shunt for deployment within a bifurcated prosthesis, wherein the shunt comprises a liner supported by a frame having a trunk portion, a branch portion, and a branch port portion so that the frame is highly stable when the shunt is expanded within the bifurcated prosthesis.

Figs. 5A & B illustrate the deployment of a bifurcated endoluminal prosthesis to provide therapy for an abdominal aortic aneurysm when both iliac arteries are accessible.

Fig. 6 illustrates an abdominal aortic aneurysm having a geometry which complicates deployment of the branch prosthesis between the branch port of the bifurcated prosthesis and the second of the two iliac arteries.

Figs. 7A-D illustrate a method for deploying a shunt within a bifurcated endoluminal prosthesis to effectively provide a single-lumen prosthetic therapy, a portion of the bifurcated prosthesis being broken away to show deployment of the shunt therein, and also shows a femorofemoral bypass and occlusion of one iliac artery with detachable balloons so as to isolate an abdominal aortic aneurysm, according to the principles of the present invention.

Fig. 8A illustrates an alternative method for occluding the port of a bifurcated endoluminal prosthesis by

deploying a self supporting tubular body within the bifurcated prosthesis, and by ligating one of the iliac arteries.

Figs. 8B-D illustrate still further alternative methods for occluding the branch port of a bifurcated endoluminal prosthesis, according to the principles of the present invention.

Fig. 9 illustrates an alternative single-lumen/bifurcated prosthetic structure and method, in which a port of the bifurcated prosthesis is initially sealed by a membrane when the bifurcated prosthesis is deployed, and in which the membrane is removed and/or opened when the branch port proves to be accessible for deployment of a branch prosthesis therein.

Figs. 10A-D illustrate bifurcated endoluminal prostheses which are initially deployed in a body lumen system with a port in a reversibly sealed configuration, and in which the port may be opened to accommodate a branch prosthesis.

Fig. 11 illustrates an axi-symmetrical bifurcation shunt for sealing a port of a bifurcated prosthesis, in which the shunt need not be positioned with any particular rotational orientation about its longitudinal axis to provide sealing.

Figs. 11A-K illustrate the structure and use of radiopaque markers having differing fluoroscopic images to differentiate, orient, and align prosthetic modules within a body lumen.

Figs. 12A and B illustrate a shunt which occludes a port of a bifurcated prosthesis from within the port.

Figs. 13-13C illustrate a preferred occluder for blocking a body lumen, together with a delivery system and method for its use.

#### **DESCRIPTION OF THE SPECIFIC EMBODIMENTS**

The present invention provides methods and systems which make use of radially expansible tubular prostheses, particularly grafts, stents, and stent-grafts. The methods, systems, and prostheses of the present invention are suitable for a wide variety of therapeutic uses, including stenting of

bifurcated body lumens such as the bronchi, trachea, carotid, and the like. The structures and methods of the present invention will find their most immediate use as endovascular prostheses for the treatment of diseases of the vasculature, particularly aneurysms, stenoses, and the like. These prosthetic methods will generally make use of structures which are radially expansible from a narrow diameter configuration (to facilitate introduction into the body lumen) to a larger diameter deployed configuration when deployed.

An exemplary cylindrical graft structure 10 is illustrated in Fig. 1. Prosthesis 10 comprises a preferred tubular frame 12 which includes a plurality of independent (non-connected) ring frames 14. The tubular frame 12 supports an inner liner 18. Optionally, an outer liner is disposed over the ring frames, either instead of inner liner 18, or in combination therewith.

To secure ring frames 14 in place, and to secure the liner to the preferred tubular frame 12, the liner is typically sutured to the frame. A wide variety of alternative liner frame attachment mechanisms are available, including adhesive bonding, heat welding, ultrasonic welding, and the like. Where inner and outer liners are used, the ring frames may be sandwiched between the liners and held in place by attaching the liners to each other. Alternative stent-graft structures are more fully described in Application Serial No. 08/538,706, filed October 3, 1995 (Attorney Docket No. 16380-003800), the full disclosure of which is hereby incorporated by reference.

Referring now to Fig. 2, an exemplary delivery catheter 30 for use with the endoluminal methods and systems of the present invention comprises a tubular cover 32 and a shaft 34. Cover 32 has a central lumen 36 extending from a proximal end 38 to a distal end 40. Shaft 34 is slidably received within central lumen 36 and extends proximally of cover 32. A plurality of axial runners 42 extend distally from shaft 34. Runners 42 line a portion of the inner surface of lumen 36, and slide within the lumen of the shaft. Shaft 34 also has a lumen, in which a core shaft 44 is slidably

disposed. Core shaft 44 has a guidewire lumen 46, while nosecone 48 is fixed to the distal end of core shaft 44, allowing the nosecone to be manipulated independently of runners 42.

5           Runners 42 are generally formed from a material which is harder than the surrounding catheter body, and thereby distribute the expansion load of prosthesis 10 over the inner surface of central lumen 36. Exemplary methods and devices for prosthetic deployment are more fully described in  
10 co-pending U.S. Patent Application Serial No. 08/475,200, filed June 7, 1995 (Attorney Docket No. 16380-001130), the full disclosure of which is also incorporated herein by reference.

          Referring now to Fig. 3, an exemplary bifurcated  
15 endovascular prosthesis 60 comprises a lumen separation portion 62 between a trunk portion 64 and two branch portions 68. Lumen separation portion 62 preferably comprises a relatively rigid structure, while trunk portion 64 and branch  
20 portions 68 preferably provide a relatively high axial flexibility. Trunk sealing cuff 66 and branch sealing cuffs 70 securely anchor and seal the prosthetic lumen against the surrounding endolithium of the body lumen system beyond the aneurysm. The specific structures of these locally optimized  
25 prostheses are more fully explained in co-pending U.S. Patent Application Serial No. 08/615,697, filed March 13, 1996 (Attorney Docket No. 16380-004100), the full disclosure of which has previously been incorporated by reference.

          Advantageously, bifurcated prosthesis 60 is generally assembled *in situ* by first expanding trunk portion  
30 64, separation portion 62, and one of the branch portions 68 within the aorta and one of the iliac arteries. The second branch portion 68 is then expanded within the open branch port 72 of separation portion 62, thereby allowing the aneurysm to be isolated by trunk sealing cuff 66 and branch sealing cuffs  
35 70.

          An endoluminal prosthesis system 80 is schematically illustrated in Fig. 4A. A bifurcated prosthesis 82 includes a trunk portion 84, a branch portion 83, and an open second



branch port 86. When possible, it is generally preferable to completely deploy branch prosthesis 88 by radially expanding end 90 within branch port 86 so that the branch prosthesis provides a direct prosthetic lumen from the aorta to the healthy portion of the adjacent iliac. However, where direct connection of the aorta and iliac are not feasible, the present system further provides a shunt 92 having a trunk sealing end 94 and a branch sealing end 96. When required, the shunt can be radially expanded within the bifurcated prosthesis so as to seal off branch port 86. Generally, shunt 92 will include a membrane 98 which is substantially impermeable, so that the shunt provides an effective seal or barrier against fluid communication with branch port 86, and so that the shunt re-directs the luminal flow.

A particularly stable shunt structure 91 is illustrated in Fig. 4B. Stable shunt 91 comprises a liner 93 supported by a perforate, radially expandable frame having a trunk portion 95, a branch portion 97, and a branch port portion 99. When deployed, the frame expands within the prosthetic luminal intersection of bifurcated prosthesis 84 as shown. The shunt's port portion 99 helps ensure that the position will be highly stable, and that there is little possibility that the shunt will move inadvertently. Preferably, the liner tapers smoothly from the trunk portion to the branch portion to minimize stagnation zones which could otherwise promote the formation of thrombus.

The deployment of bifurcated prosthesis 82, including the *in situ* assembly of branch prosthesis 88, is seen most clearly in Figs. 5A and B. Generally, the bifurcated prosthesis is radially compressed within delivery catheter 30, and the delivery catheter is introduced into the vascular system, typically using either a percutaneous or cut-down procedure. Bifurcated prosthesis 82 is positioned across an abdominal aortic aneurysm AA so that the trunk portion 84 extends into the aorta A, while the branch portion extends into a first iliac I1. Preferably, branch port 86 is radially oriented toward the alternate iliac I2, generally under the guidance of fluoroscopy and/or intravascular ultrasound

(IVUS), and with the assistance of asymmetric markings on nosecone 48, markings on the prosthesis itself, and the like.

Once the compressed bifurcated prosthesis is properly positioned, deployment begins by retracting the outer sheath of catheter 30 while maintaining the position of shaft 34. Runners 42 flex outward with the expanding prosthesis as shown. Once the prosthesis is fully released, the axial runners can be withdrawn into the sheath of the catheter, and the catheter can be withdrawn.

If all goes well, branch prosthesis 88 may be positioned so that it extends from branch port 86 to alternate iliac I2, as shown in Fig. 5B. The branch prosthesis may then be expanded into sealing engagement with the bifurcated prosthesis to complete the deployment of the bifurcated prosthetic system. Advantageously, the prosthetic lumen of this completed system provides a direct, smooth flow of blood to each of the first and second iliac I1, I2, without straining the weakened vascular wall forming the abdominal aortic aneurysm AA.

Unfortunately, not all diseased vascular geometries provide such easy access for completion of the bifurcated prosthetic system. As illustrated in Fig. 6, a highly convoluted aneurysm CA has distorted the aortoiliac junction so that completion of the bifurcated prosthetic system is not feasible. In fact, even if it were possible to position the delivery catheter from the bifurcated prosthesis to the alternate iliac I2, expansion of the branch prosthesis across this acute angle may well strain the convoluted aneurysm so as to cause a rupture, or may release the loose thrombus from within the aneurysm to the surrounding blood stream.

Such situations may arise from a variety of causes, including folds in the aneurysm which were not clearly visible under imaging, from inaccurately positioned bifurcated prostheses, and the like. Alternatively, thrombus may have accumulated in connection with the aneurysm, or the iliaci may be occluded by plaque or the like. In the advanced stages, aneurysms may lead to extreme tortuosity of the iliac so as to prevent passage of the guidewire and/or catheter, or

tortuosity of the aorta upstream of the aneurysm may prevent alignment of the branch port with the iliac. A preferred method for using shunt 92 to overcome such situations will be explained with reference to Figs. 7A-D.

5 Shunt 92 is also introduced into the vascular system compressed within a delivery catheter, as described above. Shunt 92 is positioned within bifurcated prosthesis 82 (shown in Figs. 7A-8 in a partial cut away view) so that the shunt extends from the trunk portion 84 to the branch portion 83.  
10 The shunt is then expanded, typically by withdrawing a sheath of the delivery catheter while holding the axial position of the shunt, as was also described above.

As shunt 92 expands, it engages the surrounding lumen of the bifurcated prosthesis, typically sealing against  
15 a trunk lumen 100 within the trunk portion, and against a branch lumen 102 within the branch portion. As the bifurcated prosthesis is generally sealed against the aorta and first iliac, sealing off of branch port 86 with shunt 92 will generally isolate the convoluted artery CA from the direct  
20 pressure from blood flow therethrough, as illustrated in Fig. 7C. Ideally, the shunt will also provide a smoothly tapering prosthetic lumen to minimize the strain on the heart, and to avoid areas of blood stagnation which might otherwise lead to the formation of thrombus.

25 The structure of shunt 92 is typically similar to other tubular endoluminal prostheses, ideally comprising an external perforated frame 104 supporting a substantially impermeable liner 106. The ends of the shunt may include sealing cuffs comparable to those described above. Often  
30 times, the frame will expand resiliently against the surrounding bifurcated prosthetic lumen, and may include barbs or other protruding structures to firmly affix the position of the shunt against the surrounding bifurcated prosthesis. Advantageously, there is little risk of injury to the tissue  
35 itself, which may be at some distance from this prosthetic lumen.

The liner may comprise a woven polyester such as Dacron™, or may alternatively include partially oriented yarn,

PTFE, or some other radially expansible material, as more fully explained in co-pending U.S. Patent Application Serial No. 08/595,944, filed February 6, 1996 (Attorney Docket No. 16380-004010) the full disclosure of which is incorporated  
5 herein by reference. Alternatively, shunt 92 may comprise a malleable structure and be plastically expanded in place with a mechanical expansion device such as a balloon catheter or the like.

Once shunt 92 has been deployed within bifurcated  
10 prosthesis 82, an alternative path for blood to alternate iliac I2 will often be provided, typically using a femorofemoral bypass technique, as is generally known in the art. Such techniques generally rely on a vascular bypass graft 108 to supply blood from a first femoral artery F1 to the alternate femoral artery F2. The aneurysm is generally  
15 fully isolated by occluding alternate iliac I2 with detachable balloons 110 or some other occlusion device.

Clearly, a wide variety of shunt structures may be provided. For example, as illustrated in Fig. 8A, a  
20 conformable self-supporting polymeric shunt having a structure similar to that described in co-pending U.S. Patent Application Serial No. 08/595,944, filed February 6, 1996 (Attorney Docket No. 16380-004010), may rely in part on the surrounding bifurcated prosthetic structure 82, and provides a  
25 soft conformable seal against the body lumen at its upstream and downstream ends 114, 116. Additionally, the alternative iliac can be occluded using ligation sutures 118, as will be recognized by those of skill in the art.

Still further embodiments of devices and methods  
30 according to the present invention are illustrated in Figs. 8B-D. Complete deployment of an integral bifurcated endoluminal prosthesis 111 may be prevented by occlusive plaque within the iliac, by tortuosity from an advanced aneurysm, or the like. Even where nominally complete  
35 positioning is accomplished, such occlusion may prevent the bifurcated prosthetic lumen system from providing an adequate bloodflow to each branch, particularly where an axial portion of the prosthesis is formed by a liner which is not radially

supported by the frame, as shown in Fig. 8C. By deploying a shunt within integral prosthesis 111, an integral branch port 113 is isolated from the luminal flow.

Optionally, the unused portion of the integral prosthesis may be detached and removed transluminally, as shown schematically in Fig. 8B. Also shown is an optional two-ringed shunt 115, which includes a tubular liner supported at either end in sealing engagement against the surrounding bifurcated prosthesis by radially expandable ring frames, thereby minimizing frame size and the volume required for the compressed shunt structure. An alternative occlusion device 117 comprises a liner supported by a radially expandable frame, wherein the liner covers at least one end to substantially isolate the aneurysm from the femoral artery.

The deployed positional stability of stable shunt 91 can be understood with reference to Fig. 8D, which shows the branch port portion of the shunt frame. This frame structure helps to affix the shunt at the luminal intersection. The upstream and downstream ends of the liner seal against the surrounding prosthetic lumen, the liner optionally being sewn to the end of the frame, folded over the end of the frame, or the like. Additionally, in this embodiment of the present method, the bifurcated prosthesis adjacent the branch port engages the second iliac to help isolate the aneurysm.

In a still further alternative, a bifurcated prosthesis 120 includes a prosthetic lumen 122 which is initially isolated from a branch port 126 by a removable membrane 124. Membrane 124 is releasably secured to the prosthesis using frangible sutures 128. This allows alternative bifurcated prosthesis 120 to be used as either a bifurcated or single-lumen prosthesis, as removable membrane 124 can be removed once it has been found that branch port 126 is accessible for deployment of a branch prosthesis between the alternate iliac I2 and the branch port. Removal is shown here using a barbed tool 132 positioned through a removal catheter 130. Alternatively, the membrane could be dilated, dissolved, or otherwise opened to allow fluid communication using a wide variety of structures.

The structure and operation of an openable bifurcated prosthesis 140 having a reversibly sealed port 142 are illustrated in Figs. 10A and B. A valve 144 substantially prevents fluid communication between the trunk and first branch lumens of the prosthesis and port 142 when the prosthesis is initially deployed. If port 142 is inaccessible in the body lumen system (or if second branch prosthesis deployment is otherwise problematic), valve 144 may be left sealed, and a femorofemoral bypass can be provided to supply blood to alternate iliac I2, as described above. However, where practical, it will generally be preferable to deploy a branch prosthesis in port 142 by inserting branch deployment catheter 88 through valve 144. Valve 144 may have a resilient structure similar in operation to known duck-bill valves. Valve 144 is preferably radially compressible to a small cross-section for insertion with the prosthesis, and is ideally compressible against the surrounding prosthetic lumen to minimize occlusion of branch flow through the port. Sealing between the branch prosthesis and the bifurcated prosthesis may be effected by engagement between these structures upstream and/or downstream of valve 144.

Alternative valve structures are illustrated in Figs. 10C and D. Balloon openable bifurcated prosthesis 160 includes a plastically deformable port 162 which can remain sealed when the prosthesis is deployed in the body lumen system, or which can be opened by a balloon catheter 164 inserted over a guidewire 166 using a superior approach. The orifice of such a plastically deformable port may be lined with flexible liner material to substantially prevent flow through the unopened port. Opening of plastically deformable port may be facilitated by repeated inflating, deflating, advancing, and re-inflating of balloon catheter 164. Once the port is opened, the branch prosthesis may be deployed as described above.

An upwardly oriented orifice 168 is defined by an everted portion of inner liner 170. The everted portion of the liner is supported by frame extensions 172 that extend radially inwardly and upwardly from the frame adjacent the

port. Such frame extensions may be resiliently deflectable to act as a resiliently sealing valve, or may be plastically deformable. Where the frame comprises a shape memory alloy such as that sold under the trademark Nitinol, the frame extensions may optionally be heat treated or otherwise processed to provide an  $A_c$  of over 30 degrees C, so that the port remains closed till mechanically opened by a balloon catheter or the like.

Referring now to Fig. 11, an axi-symmetric shunt 180 includes an axi-symmetric liner 182 which tapers from a trunk end 184 down to a branch end 186. A series of independent ring frames 188 externally support the liner, with the liner being crown stitched along the perimeter of the end ring frames to enhance the seal between the shunt and a surrounding bifurcated prosthesis, as more fully described in co-pending U.S. Patent Application 08/538,706, filed October 3, 1995 (Attorney Docket No. 16380-003800), the full disclosure of which is incorporated by reference. Two of the ring frames are heat-treated to assume a tapered configuration, thereby supporting a tapered portion of the liner. The liner may be sewn, chemically compacted, or plastically expanded along a portion of its axial length to provide the tapering shape, but will preferably be continuously woven with more tightly woven axial threads adjacent the trunk end than adjacent the branch end. The density of the liner may be kept consistent by varying the number of circumferential threads per inch. Round radiopaque markers 190 are sewn to the liner to help identify and position the ends of the shunt under fluoroscopy, as can be understood with reference to U.S. Patent Application 08/628,797, filed April 5, 1996 (Attorney Docket No. 16380-005600). The use of markers having differing shapes on the bifurcated prosthesis and the shunt helps to avoid confusion between the images of the markers on these two structures. A particular advantage of such an axi-symmetric shunt is that the shunt can be deployed within a bifurcated prosthesis without having to rotationally position the shunt, and can still provide a smooth, well anchored transition from the large trunk lumen to the smaller branch lumen.

The structure, use, and advantages of differing markers on the prosthetic modules of a modular prosthetic system can be understood with reference to Figs. 11A-K. An elongate bar marker 201 is affixed by sutures 203 to an outer surface of liner 18, here within an opening 205 of ringframe 14. Bar marker 201 comprises a radiodense material such as gold, platinum, tantalum, or the like, ideally being formed from tantalum and having a thickness of about 0.01 inches, a width of about 0.04 inches, and a length of about 0.1 inches. Such markers may be produced by laser cutting, EDM cutting, presses, or mechanical punching, from flat sheets, solid stock, tubes, or bars. Alternatively, radiopaque markers may be applied as a paint including tantalum or some other radiodense material, or formed from a polymer having a radiodense material. Similar markers may be provided for imaging under ultrasound, magnetic resonance imaging, or the like.

A torroidal marker 207 has a similar structure and size, but produces an image under fluoroscopy which is very different than that of bar marker 201. Torroidal marker 207 may be stitched, bonded, fastened, ultrasonically welded, or otherwise permanently attached to a second module of an endoluminal prosthetic system. The differing images of these structures can help to avoid confusion between a bifurcated prosthesis and an adjacent branch prosthesis, shunt, sealing cuff, or any other module of the prosthesis system when the system is imaged during or after deployment. Alternative marker shapes which produce a variety of distinguishable images include a triangular opening marker 209, round marker 190, an obtuse marker 213, and an acute marker 215, as illustrated in Figs 11E-H.

Methods for using differing marker shapes are illustrated by schematic images of prosthetic systems in Figs. 11I-K. Bifurcated prosthesis 82 includes a pattern of marker bars 201, while the position of the ends of axi-symmetric shunt 180 are indicated by torroidal markers 207, so that the differing markers can be easily distinguished even when the modules overlap and are viewed under fluoroscopy. Hence, Fig.



11I is an example of image differentiation using differing marker shapes.

Fig. 11J is an example of image orientation using differing markers. The pattern of marker bars 201 on bifurcated prosthesis 82 indicates the orientation of that structure. This allows the physician to orient the modular components in rotational, axial, angular, and linear positions. By using different marker shapes, densities, or the like, the physician can readily position each modular prosthetic system component at the desired location.

Fig. 11K illustrates the use of marker shapes to enhance alignment of the marker images. In this example, an image of obtuse marker 213 on branch prosthesis 88 is aligned with an image of obtuse marker 213 on an extender cuff prosthesis 219 to indicate that sufficient overlap has been achieved. Generally, the differing markers of the present invention allow the physician to match, align, or overlap the markers to create joints, seals, or attachment points, greatly facilitating the accurate assembly of modular endovascular prostheses under fluoroscopy and other remote imaging modalities.

A still further shunt structure is illustrated in Figs. 12A and B. In this embodiment, an occluding shunt 200 is deployable within the port of the bifurcated prosthesis. Occluding shunt 200 has an open end 202 and a closed end 204, and may have either an inner or outer liner 206 supported by a frame 208. To help provide a smooth transition, occluding shunt 200 may have a concave surface 210 adjacent closed end 204, as shown in cross-section in Fig. 12B. Occluding shunt 200 substantially seals the port of the bifurcated prosthesis from within the port, and does not diminish the size of the open branch lumen.

An exemplary occluder 220 for preventing flow through a body lumen is illustrated in Fig. 13. Occluder 220 includes a woven polyester tubular liner 222 which extends axially beyond a frame 224. Liner 222 is closed at both ends by sealing sutures 226, so that sutures 226 are axially displaced from the frame. This prevents the sutures (or the

liner which is bunched together by sutures 226) from interfering with radial compression of frame 224, thereby enhancing the radial compressibility of the structure. The liner will also often extend beyond the frame when the frame is expanded to provide an easily deformable extension which encases thrombus, the liner being a flexible material which accommodates tissue ingrowth and admits blood during expansion, but which prevents significant bloodflow through the lumen once expanded.

As illustrated in Fig. 13A, occluder 220 may be deployed in a body lumen 228 using many of the deployment structures described above. To provide guidewire access through the closed ends of liner 222, inner member 230 optionally penetrates the extended ends of the liner. Sutures 226 may optionally be formed of an elastic material to seal the liner when inner member 230 is withdrawn proximally. Alternatively, the liner ends may be closed with no guidewire access therethrough, and a rapid exchange guidewire external to sheath 30 may be used, so that the occluder is deployed by simply withdrawing the sheath proximally.

Referring now to Fig. 13B and C, an alternative occluder 240 includes integral proximal and distal inner members 242, 246. These integral members are attached to the liner to allow guidewire access through the compressed occluder within the delivery system. Alternatively, a single contiguous inner member may also be used. An atraumatic distal tip 250 on catheter sheath 30 includes deformable segments 252 to pass the occluder, and to present a safe distal surface without a nosecone. In some embodiments, an occluder may include a single luminal flow barrier (rather than having both ends closed), while the optional integral guidewire lumen may be contiguous through both ends when both ends are sealed. The radially compressible port sealing structures described above may also be adapted for use in a permanent or openable occluder.

Although the foregoing invention has been described in some detail, by way of illustration and example, for purposes of clarity of understanding, certain changes and

modifications will be obvious to those of skill in the art. For example, a similar bifurcated prostheses deployed within an iliac artery and having a port intended to supply blood for a hypogastric artery may benefit from a shunt or a releasably sealable port where coupling the port to the hypogastric artery is problematic. Therefore, the scope of the present invention is limited solely by the scope of the appended claims.

5

WHAT IS CLAIMED IS:

1           1. A method for repairing a bifurcated body lumen  
2           system having a trunk lumen in fluid communication with first  
3           and second branch lumens at a luminal intersection, wherein  
4           a tubular bifurcated endoluminal prosthesis is deployed within  
5           the body lumen system so that a trunk portion of the  
6           prosthesis extends into the trunk lumen and a first branch  
7           portion of the prosthesis extends into the first branch lumen,  
8           and wherein a second branch port of the prosthesis is disposed  
9           between the trunk and branch portions, the method comprising  
10          substantially sealing the second branch port of the prosthesis  
11          to prevent fluid communication between the prosthetic trunk  
12          lumen and the body lumen system through the second branch  
13          port.

1           2. A method as claimed in claim 1, further  
2           comprising providing a passage for fluid communication between  
3           the first branch lumen and the second branch lumen of the body  
4           lumen system.

1           3. A method as claimed in claim 1, wherein the  
2           sealing step comprises deploying a shunt within the bifurcated  
3           prosthesis so that the shunt extends from the trunk portion to  
4           the branch portion, and so that a membrane of the shunt  
5           substantially blocks fluid communication between the  
6           prosthetic trunk lumen and the second branch port of the  
7           bifurcated prosthesis.

1           4. A method as claimed in claim 3, further  
2           comprising sealingly engaging the membrane against the  
3           prosthetic trunk lumen, the membrane comprising a tubular  
4           liner.

1           5. A method as claimed in claim 3, further  
2           comprising sealingly engaging the membrane against a  
3           prosthetic first branch lumen within the branch portion of the  
4           bifurcated prosthesis.

1           6. A method as claimed in claim 3, further  
2 comprising sealingly engaging the membrane directly against at  
3 least one of the trunk lumen of the body lumen system and the  
4 branch lumen of the body lumen system, the shunt extending  
5 axially beyond at least one of the branch portion and the  
6 trunk portion of the bifurcated prosthesis.

1           7. A method as claimed in claim 3, further  
2 comprising deploying the shunt with a cross-section which  
3 transitions smoothly between a trunk cross-section of the  
4 prosthetic trunk lumen and a branch cross-section of a  
5 prosthetic branch lumen of the branch portion.

1           8. A method for repairing an aneurysm of an  
2 abdominal aortic artery adjacent first and second iliac  
3 arteries, the method comprising:  
4           deploying a bifurcated tubular endoluminal  
5 prosthesis within the aneurysm so that a trunk portion of the  
6 prosthesis having a trunk lumen extends into the aorta and a  
7 first branch portion of the prosthesis having a first branch  
8 lumen extends into the first iliac, wherein a second branch  
9 port of the prosthesis is disposed between the trunk and  
10 branch portions;

11           deploying a shunt within the bifurcated prosthesis  
12 so that the shunt extends from the trunk lumen to the branch  
13 lumen, and so that the shunt substantially blocks fluid  
14 communication between the prosthetic trunk lumen and the  
15 second branch port of the bifurcated prosthesis.

1           9. A method as claimed in claim 8, further  
2 comprising determining that the second branch port of the  
3 bifurcated prosthesis is substantially inaccessible for  
4 deployment of a second tubular branch endoluminal prosthesis  
5 extending from the second branch port into the second iliac  
6 before deploying the shunt.

1           10. A method as claimed in claim 8, further  
2 comprising providing a femorofemoral bypass so as to allow

1 blood flow from a first femoral artery adjacent the first  
2 iliac to a second femoral artery adjacent the second iliac.

1 11. A method as claimed in claim 8, further  
2 comprising occluding the second iliac between the aneurysm and  
3 the femorofemoral bypass so as to prevent blood from flowing  
4 back through the second iliac into the aneurysm.

1 12. A method for repairing an aneurysm of an  
2 abdominal aortic artery adjacent first and second iliac  
3 arteries, after deploying a bifurcated endoluminal prosthesis  
4 within the aneurysm so that a trunk portion of the prosthesis  
5 extends into the aorta and a first branch portion of the  
6 prosthesis extends into the first iliac, wherein a second  
7 branch port of the prosthesis is disposed between the trunk  
8 and branch portions, and wherein the second branch port of the  
9 bifurcated prosthesis is inaccessible for deployment of a  
10 tubular second branch endoluminal prosthesis therein, the  
11 method comprising;

12 deploying a shunt within the bifurcated prosthesis  
13 so that the shunt extends from the trunk portion to the branch  
14 portion of the bifurcated prosthesis, and so that the shunt  
15 substantially blocks blood flow from the prosthetic trunk  
16 lumen to the second branch port of the bifurcated prosthesis,  
17 wherein the shunt does not substantially occlude blood flow  
18 between the trunk lumen and the branch lumen of the bifurcated  
19 prosthesis.

1 13. A shunt for use with a bifurcated tubular  
2 endoluminal prosthesis, the bifurcated prosthesis having a  
3 branch lumen in fluid communication with a trunk lumen and a  
4 branch port disposed therebetween, the shunt comprising:  
5 a substantially impermeable membrane; and  
6 a support structure capable of affixing the  
7 impermeable membrane within the bifurcated prosthesis so that  
8 the impermeable membrane blocks fluid communication between  
9 the trunk lumen and the branch port of the bifurcated  
10 prosthesis, wherein the shunt will not substantially occlude

1 fluid communication between the trunk lumen and the branch  
2 lumen when the membrane is affixed within the prosthesis by  
3 the support structure.

1 14. A shunt as claimed in claim 13, wherein the  
2 support structure comprises a radially expandable tubular  
3 body.

1 15. A shunt as claimed in claim 14, wherein the  
2 tubular body comprises a perforate frame, and wherein the  
3 membrane comprises a liner supported by the frame.

1 16. A shunt as claimed in claim 15, wherein the  
2 membrane is formed integrally with the tubular body.

1 17. A shunt as claimed in claim 15, wherein a trunk  
2 end of the shunt seals radially against the trunk lumen of the  
3 bifurcated prosthesis when expanded therein.

1 18. A shunt as claimed in claim 17, wherein a  
2 branch end of the shunt opposite the trunk end seals radially  
3 against the branch lumen of the bifurcated prosthesis when  
4 expanded therein.

1 19. A shunt as claimed in claim 15, wherein a  
2 branch end of the shunt is capable of sealing radially against  
3 a surrounding lumen having a branch cross-section, and wherein  
4 a trunk end of the shunt opposite the branch end is capable of  
5 sealing radially against a surrounding lumen having a trunk  
6 cross-section which is at least twice as large as the branch  
7 cross-section.

1 20. A shunt as claimed in claim 19, wherein a  
2 length of the shunt between the branch end and the trunk end  
3 is longer than the bifurcated prosthesis, and wherein the ends  
4 of the prosthesis are adapted to seal atraumatically against a  
5 surrounding body lumen.

1           21. A shunt as claimed in claim 14, wherein the  
2 shunt has a shunt lumen which tapers between a trunk cross-  
3 section within the trunk lumen and a branch cross-section  
4 within the branch lumen when the shunt is deployed within the  
5 bifurcated prosthesis.

1           22. A system for repairing a diseased body lumen  
2 system, the repair system comprising:  
3           a bifurcated tubular endoluminal prosthesis having a  
4 trunk portion with a trunk lumen, a first branch portion  
5 having a first branch lumen, and a second branch port in fluid  
6 communication with the trunk lumen; and  
7           a shunt including a substantially impermeable  
8 membrane and a support structure capable of affixing the  
9 impermeable membrane to the bifurcated prosthesis so that the  
10 impermeable membrane blocks fluid communication between the  
11 trunk lumen and the second branch port of the bifurcated  
12 prosthesis.

1           23. A repair system as claimed in claim 22, wherein  
2 the support structure comprises a tubular, radially expandable  
3 body.

1           24. A repair system as claimed in claim 23, wherein  
2 the tubular body comprises a perforate frame, and wherein the  
3 membrane comprises a liner supported by the frame.

1           25. A repair system as claimed in claim 23, wherein  
2 the membrane is formed integrally with the tubular body.

1           26. A repair system as claimed in claim 23, wherein  
2 a trunk end of the shunt is adapted to seal radially against  
3 at least one of the trunk lumen of the bifurcated prosthesis  
4 and the trunk lumen of the body lumen system when expanded  
5 therein.

1           27. A repair system as claimed in claim 26, wherein  
2 a branch end of the shunt opposite the trunk end is adapted to



1 seal radially against at least one of the branch lumen of the  
2 bifurcated prosthesis and the trunk lumen of the body lumen  
3 system when expanded therein.

1 28. A repair system as claimed in claim 27, wherein  
2 the branch end of the shunt is capable of sealing radially  
3 against a surrounding lumen having a branch cross-section, and  
4 wherein the trunk end of the shunt is capable of sealing  
5 radially against a surrounding lumen having a trunk cross-  
6 section which is at least twice as large as the branch cross-  
7 section.

1 29. A repair system as claimed in claim 22, further  
2 comprising a branch tubular prosthesis having an end which  
3 sealingly engages the branch port of the bifurcated prosthesis  
4 when expanded therein.

1 30. A repair system as claimed in claim 22, wherein  
2 the assembled system provides a prosthetic lumen system which  
3 tapers smoothly from the trunk portion to the branch portion  
4 so as to minimize stagnation of luminal flow.

1 31. A repair system as claimed in claim 22, wherein  
2 the shunt comprises a frame which expands within at least one  
3 of the trunk portion and the branch port of the bifurcated  
4 prosthesis to a cross-section which is larger than a branch  
5 cross-section of the branch lumen so as to stabilize the  
6 position of the shunt.

1 32. A method for repairing a bifurcated body lumen  
2 system, the method comprising:  
3 inserting a bifurcated prosthesis into the lumen  
4 system so that a first lumen of the of the prosthesis  
5 sealingly engages a first lumen of the body system, so that a  
6 second lumen of the prosthesis sealingly engages a second  
7 lumen of the body lumen system, and so that a port of the  
8 prosthesis is adjacent a third lumen of the body lumen system,

wherein the port is reversibly sealed to substantially prevent flow through the port.

33. A method as claimed in claim 32, further comprising opening the port in situ to provide fluid communication between the first lumen and the third lumen of the body lumen system.

34. A method as claimed in claim 33, further comprising inserting a balloon catheter into the sealed port, plastically expanding the port with the balloon, and deploying a branch prosthesis within the expanded port.

35. A bifurcated endoluminal prosthesis comprising: a tubular body which is radially expandable from a narrow configuration for endoluminal introduction to a large configuration, the body in the large configuration having a first lumen, a second lumen in fluid communication with the first lumen, and a reversibly sealed port disposed between the first lumen and the second lumen.

36. A bifurcated prosthesis as claimed in claim 35, wherein the port is capable of receiving a branch tubular prosthesis therein so as to provide fluid communication between the first lumen and a branch lumen of the branch prosthesis.

37. A bifurcated prosthesis as claimed in claim 35, wherein the tubular body comprises a resilient structure which radially expands when released in a body lumen, and wherein the port is plastically expandable after the tubular body is deployed in situ.

38. A system for repairing a diseased body lumen, the system comprising:

a bifurcated endoluminal prosthesis having a port disposed between and in fluid communication with first and second lumens, the prosthesis radially expandable from a

1 narrow configuration for introduction into the body lumen to a  
2 larger deployed configuration;  
3 an occluder disposable in the port of the deployed  
4 prosthesis so as to substantially seal the port.

1 39. A system as claimed in claim 38, wherein the  
2 occluder is adapted to provide a smooth transition from within  
3 the prosthesis from the first lumen to the second lumen.

1 40. An endoluminal prosthetic system comprising:  
2 a first prosthetic module having a first tubular  
3 body and a first imageable marker; and  
4 a second prosthetic module having a second tubular  
5 body which can expand radially to engage the first tubular  
6 body, and a second imageable marker adapted to provide an  
7 image which is different than an image of the first marker.

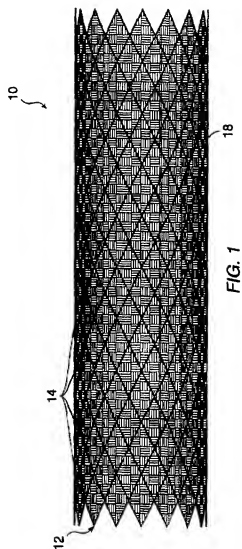
1 41. A system for occluding a body lumen, the system  
2 comprising:  
3 a tubular frame having a proximal end, a distal end,  
4 and an axis, the frame resiliently expandable from a narrow  
5 configuration to a wide configuration within the body lumen;  
6 and  
7 a liner supported by the frame, the liner adapted to  
8 occlude the body lumen when the frame is in the wide  
9 configuration, the liner extending axially beyond the frame  
10 when the frame is in the narrow configuration.

1 42. A system as claimed in claim 41, further  
2 comprising:  
3 a sheath having a lumen which receives the frame and  
4 liner, the sheath radially restraining the frame in the narrow  
5 configuration with the liner extending distally beyond the  
6 frame; and  
7 an inner member having a guidewire lumen disposed  
8 within the sheath, the inner member extending distally through  
9 the frame and liner, the sheath and inner member withdrawable  
10 proximally from the liner and frame when the frame is radially

11 expanded within the body lumen, the liner adapted to seal when  
12 the inner member is withdrawn.

1           43. A system as claimed in claim 42, further  
2 comprising an expandable atraumatic tip at the distal end of  
3 the sheath, the tip comprising a plurality of deformable  
4 segments which separate radially when the frame moves distally  
5 from within the lumen of the sheath.

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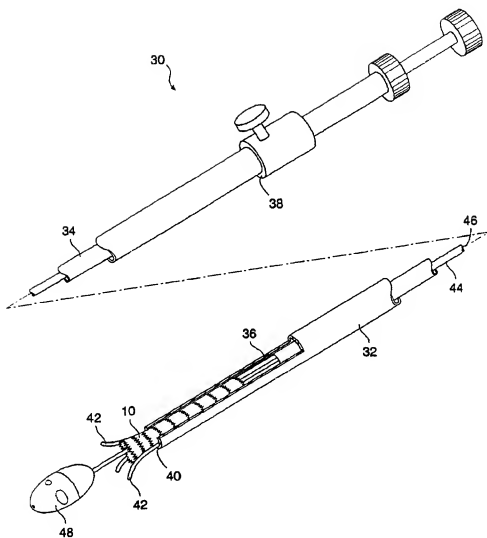


FIG. 2

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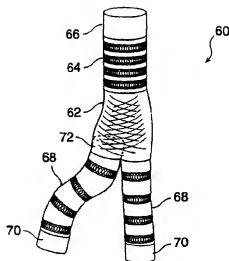


FIG. 3

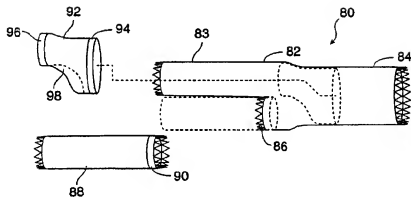


FIG. 4A

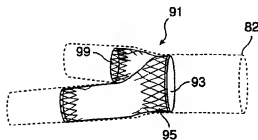


FIG. 4B

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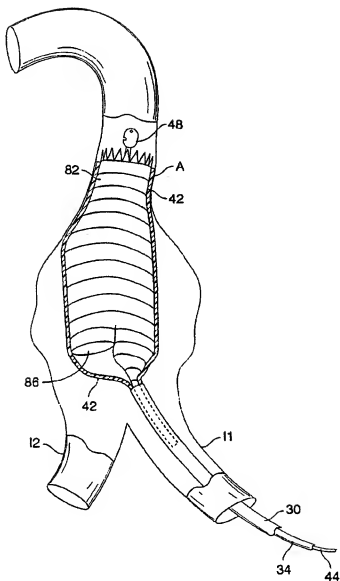


FIG. 5A



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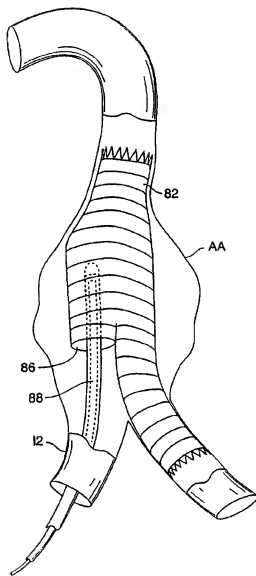


FIG. 5B

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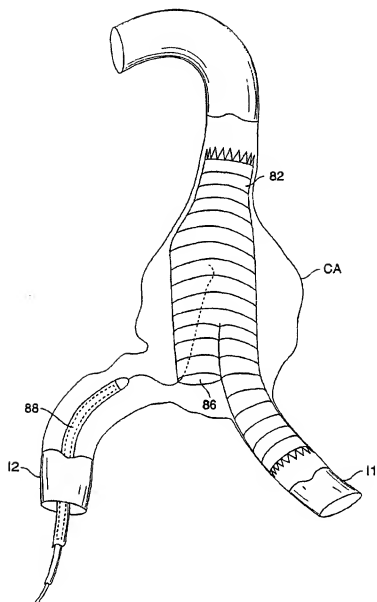


FIG. 6

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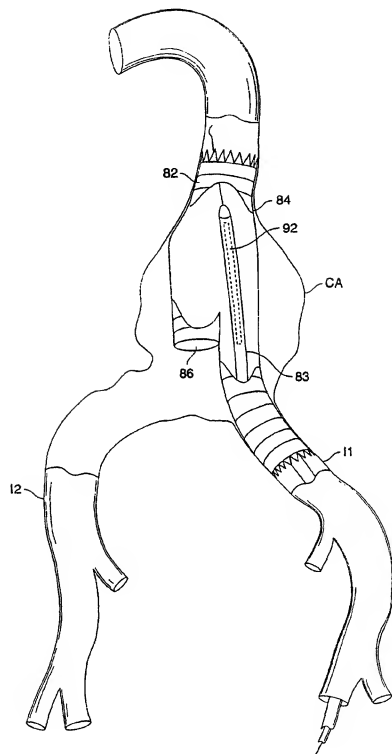


FIG. 7A

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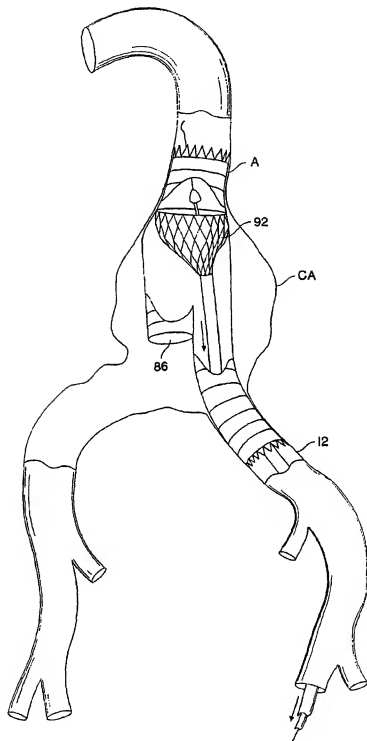


FIG. 7B

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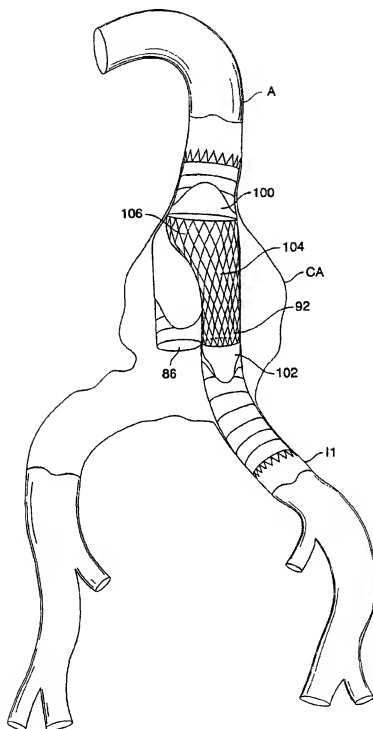
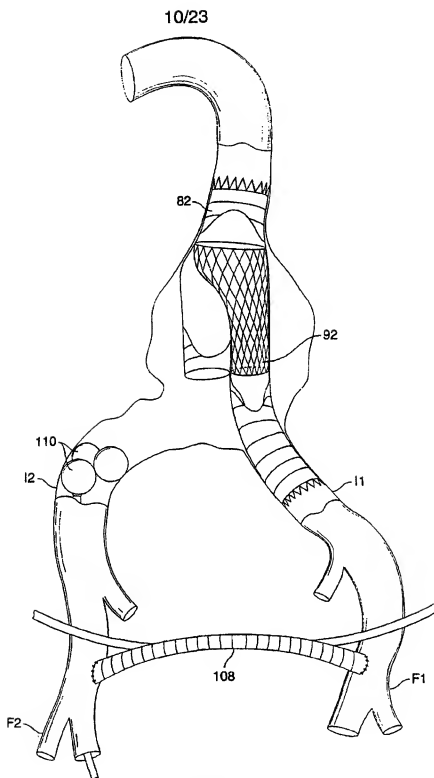


FIG. 7C

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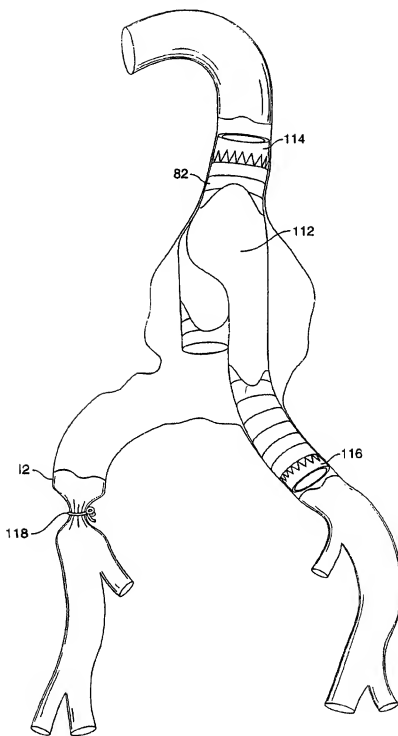


FIG. 8A

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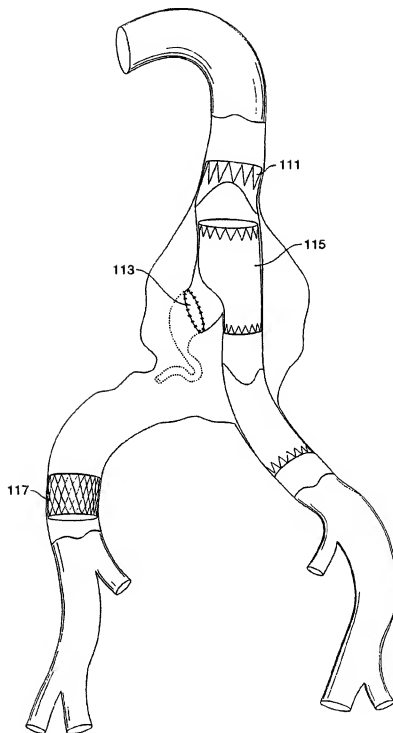


FIG. 8B



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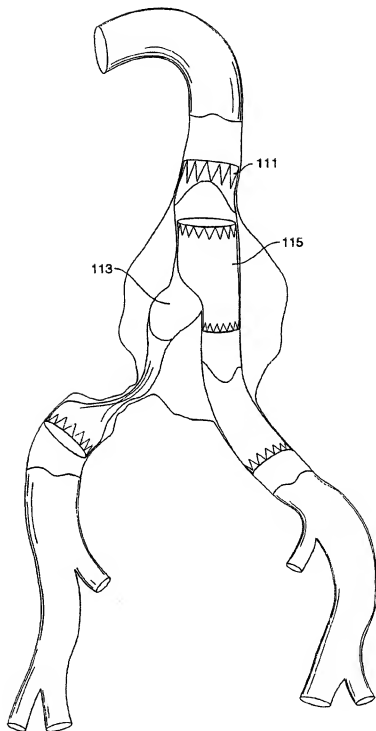


FIG. 8C

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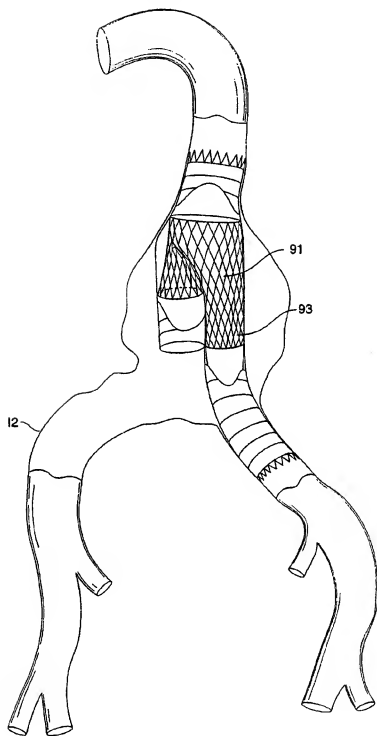


FIG. 8D

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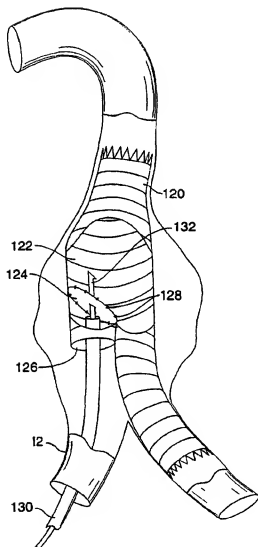


FIG. 9

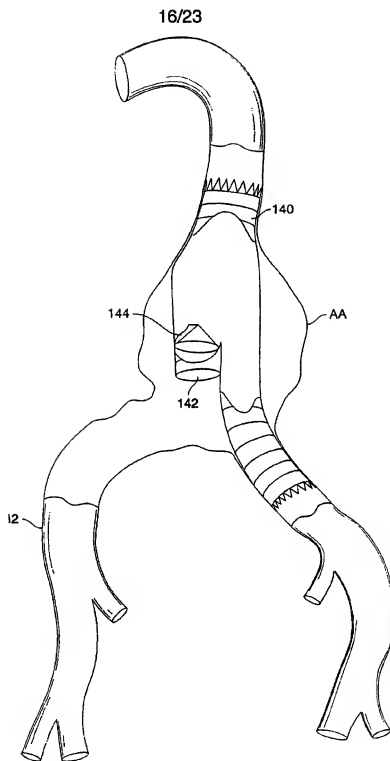


FIG. 10A

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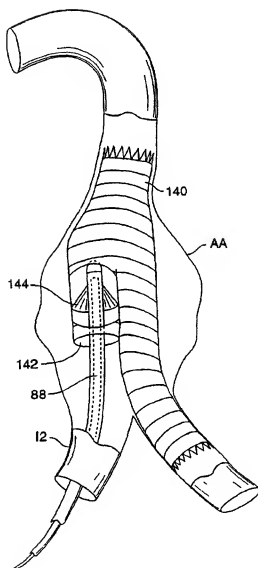


FIG. 10B

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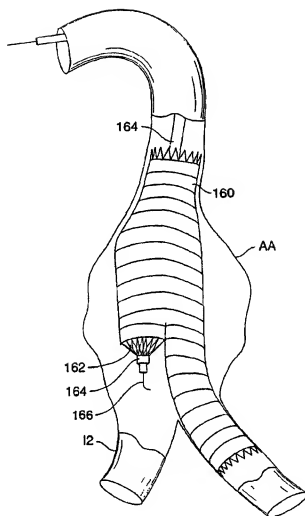


FIG. 10C

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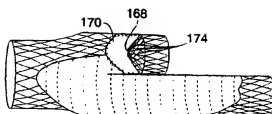


FIG. 10D

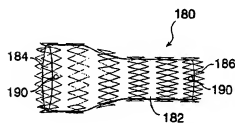


FIG. 11

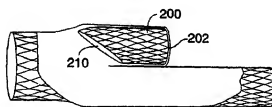


FIG. 12A

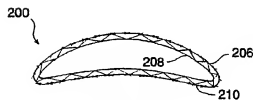


FIG. 12B

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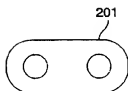


FIG. 11A

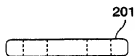


FIG. 11B

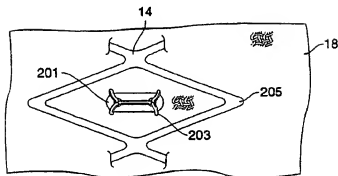


FIG. 11C

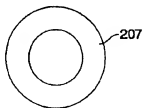


FIG. 11D

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FIG. 11E

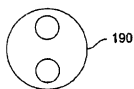


FIG. 11F



FIG. 11G

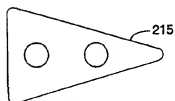


FIG. 11H

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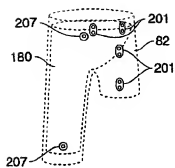


FIG. 11I

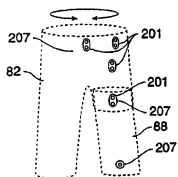


FIG. 11J

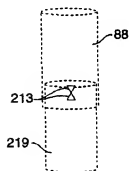


FIG. 11K

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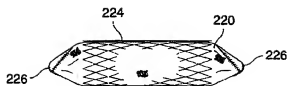


FIG. 13

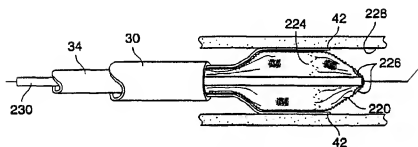


FIG. 13A



FIG. 13B

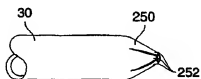


FIG. 13C

SUBSTITUTE SHEET (RULE 26)

# INTERNATIONAL SEARCH REPORT

Intern: 1 Application No  
PCT/US 97/09654

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 6 A61F2/06 A61B17/12

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 539 237 A (COOK INC.) 28 April 1993	13,14, 22,23, 29-31, 35,38-43
Y	see column 14, line 55 - column 17, line 8; claim 11; figures 20,22 ---	15-19, 24-28
Y	EP 0 667 132 A (EXPANDABLE GRAFTS PARTNERSHIP) 16 August 1995 see column 13, line 21 - column 14, line 3; figures 5,15,10A,10B ---	15-19, 24-28
X	US 5 382 261 A (J.C. PALMAZ) 17 January 1995	41
A	see the whole document  --- -/-	13-17, 22-26, 35,38

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

### \* Special categories of cited documents:

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" documents published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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- "Z" document member of the same patent family

Date of the actual completion of the international search

19 September 1997

Date of mailing of the international search report

06. 11. 97

Name and mailing address of the ISA

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NL - 2280 HV Rijswijk  
Tel.: (+ 31-70) 340-2080, Telex 31 651 epo nl,  
Fax: (+ 31-70) 340-3016

Authorized officer

Wolf, C

# INTERNATIONAL SEARCH REPORT

International Application No  
PCT/US 97/09654

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 458 649 A (K. MAKITA ET AL.) 27 November 1991 see column 2, line 18 - line 36; figures ---	35,38,39
A	J. C. PARODI: "ENDOVASCULAR REPAIR OF ABDOMINAL AORTIC ANEURYSMS AND OTHER ARTERIAL LESIONS" JOURNAL OF VASCULAR SURGERY, vol. 21, no. 4, April 1985, pages 549-557, XP002041236 cited in the application see page 555, column 1, line 25 - line 30; figure 3 ---	13,35,38
A	US 4 710 192 A (D.S. LIOTTA ET AL.) 1 December 1987 -----	

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US 97/09654

## Box I (Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet))

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 1-12  
because they relate to subject matter not required to be searched by this Authority, namely:  
RULE 39 .1 (IV) PCT
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 4(A).

## Box II (Observations where unity of invention is lacking (Continuation of item 2 of first sheet))

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.  
☐ No protest accompanied the payment of additional search fees.

## INTERNATIONAL SEARCH REPORT

International Application No.  
PCT/US 97/09654

Patent document cited in search report		Publication date		Patent family member(s)		Publication date
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US 4710192	A	01-12-87		NONE		
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